36. (New) The anhydrous lactitol crystals according to claim 4 wherein the lactulitol content is less than 0.5% by weight.

37. (New) The anhydrous lactitol crystals according to Claim 36 wherein the lactulitol content is less than 0.1% by weight.

38. (New) The process according to Claim 15 wherein the seeding is effected at a temperature of 90-80°C.

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39. (New) The process according to Claim 15 wherein in step (d) the mixture is cooled to a temperature of 70-100°C.

40. (New) The process according to Claim 39 wherein in step (d) the mixture is cooled to a temperature of 70-80°C.- -

REMARKS

The Office Action has rejected Claims 23 and 24 under 35 U.S.C. §101, alleging that the claimed invention is directed to non-statutory subject matter. In addition, Claims 3, 4 and 15 are rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to point out and distinctly claim the subject matter which applicants regard as the invention. Finally, Claims 1-22 are rejected under 35 U.S.C. §102(b), or in the alternative under 35 U.S.C. §103(a) as defining subject matter which is allegedly anticipated by or in the alternative allegedly rendered obvious by the teachings in WO 92/16545, of which Heikkila, et al. are the inventors ("Heikkila, et al.")

Applicants have cancelled Claims 23 and 24 without prejudice and have rewritten subject matter therein in new Claims 26, 27 and 28. Support is found in the last paragraph beginning on Page 8 of the instant specification. Further Claims 3 and 4 have been amended to delete the preferable language therein, which subject matter is recited in newly added Claims 35-37. In addition, Claim 15 has been amended to delete the preferable "language" therein; the deleted language has been added in new Claims 38, 39 and 40.

Claims 10, 14 and 15 have been amended to recite that the product described in the preamble of the claims has been produced by the process. Claims 29-34 have also been added to the application. Support for Claims 29-32 is found in the last paragraph of Page 8 in the instant specification. Support for the subject matter of Claims 33 and 34 is found throughout the specification, e.g., Page 8, first paragraph, and Page 3, third full paragraph.

Thus, no new matter has been added to the application.

A version with markings showing the amendments to the claims is attached hereto. It is entitled "Version With Markings To Show Changes Made."

It is to be noted that the amendments to the claims do not narrow the scope thereof.

Pursuant to the rejection of Claims 23 and 24 under 35 U.S.C. §101, the Office Action alleges that the "use" format is non-statutory. As rewritten in newly added Claims 26-28, the claims are directed to an improved composition of matter, whereby the use format has been eliminated. Thus, the rejection of Claims 23 and 24 under 35 U.S.C. §101 is obviated, withdrawal thereof is respectfully requested.

Moreover, applicants respectfully submit that the removal of the "preferably" language from Claims 3, 4 and 15 overcomes the rejection under 35 U.S.C. §112, second paragraph; withdrawal thereof is respectfully requested.

Pursuant to the rejection of the claims under 35 U.S.C. §102, or in the alternative, 35 U.S.C. §103, the Office Action cites Heikkila, et al.

Heikkila, et al. disclose lactitol α crystals; it does not teach, disclose any β-lactitols, as presently claimed. As shown in the present application the α form is quite different from the β-form. Attention is directed to Page 8 of the instant specification, which compares the α and β lactitols. As clearly shown by the data in Table 1, the α and β forms have different crystal forms, the α-lactitol form being monoclinic while the β form being

orthorhombic. Moreover, they have different spatial groups, the α having the spatial group $P2_1$ while the β lactitol having the spatial group $P2_12_12_1$. Moreover, as shown by the text, the β crystals have different properties than the α lactitols. For example, the β crystals are harder than the α crystals. Further, they have different melting enthalpies with the α form being 149 J/g, while the β form being 166-169 J/g. Moreover, as indicated in the specification, on Page 1, the α and β forms can be easily distinguished in the X-ray powder diffraction as a result of the different structures. Moreover, there are other differences between the α and β lactitols. For instance, the β lactitol crystals are very stable and they are harder than the α lactitol crystals as described on Page 8 of the specification. This gives technical advantages, e.g. in foodstuffs and special tooth pastes. Both anhydrous lactitols are non-hygroscopic, but the β lactitol absorbs water even more slowly than does the α lactitol. This makes the β lactitol even more stable than the α lactitol at storage in moist and warm conditions, thereby making products containing same more stable than similar products containing α-lactitols in lieu of the β-lactitol. The β lactitol has a lower solubility at high temperatures than the α lactitol. This affects the way the two lactitol forms dissolve in liquids during use and processing. The melting enthalpy of the β lactitol is higher than that of the α lactitol, which means that it needs more heat to melt or, contrarily, it keeps solid for a longer time without melting. Thus, the composition of matter containing β lactitols have unexpected advantages over the corresponding composition of matter containing α lactitol.

Additionally, as will be shown below in connection with a discussion on the methods, the β lactitol crystals cannot be formed under the conditions which favour the production of the α lactitol crystals. Thus, it is indeed highly unlikely that such β lactitol crystals have ever been produced even by mistake by the processes of the prior art.

Moreover, when the α lactitol is subjected to X-ray diffraction analysis, has no βlactitol form has been detected. Even considering the possibility (which is not, however, admitted) that a small amount of β lactitol could have been produced by the prior art methods and hence could have existed in a prior art product, it should be noted that a person discovering such a β lactitol form in a prior art product would not have known how to reproduce the result.

Thus, since the prior art reference is limited to lactitol in the α-form, and since the β-lactitol crystals cannot be made under the conditions favoring the production of α-lactitol crystals, the prior art reference cannot teach, disclose or suggest the claimed subject matter of the present application.

Moreover, the prior art process of Heikkila, et al. is non-enabling as to the production of the β lactitol and as such cannot destroy the novelty of the β lactitol, as claimed. A β lactitol formed by the prior art process is non-existent and hence cannot take away the patentablitliy of the β lactitol.

Thus the β lactitol has properties different from those of the α lactitol crystals produced in the prior art reference. These different properties are unexpected and have an influence on the technical utility and industrial applicability of the new lactitol form. Hence, it is respectfully submitted that the β lactitol shows an inventive step over the prior art.

Moreover, the processes of making the β lactitol are different and patentable over the prior art. As described on Page 5 of the present application, the process of making the β lactitols are different from the α lactitols. In one embodiment, as recited in Claim 10, the β lactitols are formed by conditioning the α lactitol solution. The inventive conditioning is performed in addition to the crystallization steps of the prior art and the crystallization is slow in comparison to the crystallization of the prior art.

For example, the conditioning step, as recited in the process of claim 10 is **a** very specific feature which provides the novel β lactitol. The reason for this will be explained below with reference to some theoretical considerations of crystal formation.

The inventors have noted that the β lactitol will not crystallize as easily as the α lactitol in aqueous solutions. In actual fact it has been shown that the β lactitol will not crystallize in solutions where α lactitol crystals are forming and/or growing. The β lactitol is very much slower at crystallizing and it seems that its nucleation mechanism is prohibited as long as α lactitol crystals are growing. This means that as long as the supersaturation of a crystallizing lactitol solution is maintained above the solubility line of the α lactitol, then α lactitol will crystallize and β lactitol cannot crystallize!

A person skilled in the art is well aware of the fact that during a normal cooling crystallization, the concentration of lactitol in the solution gradually diminishes as dissolved lactitol in the solution transfers from the liquid phase into the solid α crystalline phase. At the same time and in accord with the crystallization, the temperature is lowered (cooled) so that the supersaturation is kept above the solubility line of the desired α lactitol. If the crystallizer would allow the supersaturation to fall below the α lactitol saturation level (i.e. below the α lactitol solubility line) then the already crystallized α lactitol would start to dissolve. Thus, the crystallizer will keep the saturation level at a high enough level so as to have a driving force (supersaturation) creating α lactitol crystals and not a driving force (undersaturation) dissolving the α crystals.

It is only when the saturation of the solution drops to or below the solubility line of the α lactitol that the β lactitol crystals start to be generated and can grow. This does not happen during the crystallization procedures aiming at producing the α lactitol as

described in the prior art.

If the α lactitol crystals are recovered from the solution, no β lactitol is formed, since the transformation from α to β has not been observed to take place in the dry state. If the temperature of the solution is allowed to sink below about 69°C, lactitol monohydrate will start to form and no β lactitol will form.

When the procedure of claim 10 is operated, the cooling crystallization is first operated normally to provide the first (α lactitol) crystal yield. When the solution has been cooled down to the desired temperature the cooling stops and then the conditioning starts. As described in the specification the conditioning keeps the solution at a certain temperature (see also the examples which define constant conditioning temperatures of about 85 or 70 °C, respectively). During the conditioning there is thus no cooling any longer.

When the cooling stops, α lactitol crystals will continue growing until no supersaturation in regard to α lactitol remains. At this point there is no driving force left to produce α lactitol. Thus, it becomes energetically possible for β lactitol crystals to grow. β-lactitol has a lower solubility than α lactitol and thus, the solution is still supersaturated for β lactitol although it is no longer supersaturated for α lactitol. It seems that the β lactitol crystal formation mechanism is no longer prohibited when α lactitol cannot crystallize.

During the 'conditioning' defined in the present invention, the α lactitol crystals are retained in the solution without any further cooling. When the supersaturation for α lactitol crystals has been "consumed", β lactitol crystals can start to grow, and slowly, the α lactitol transforms in the solution into β lactitol at the conditioning (non-cooling) temperature. The same phenomenon is applicable to the processes described in Claim 14 and 15 and those

dependent thereon.

Thus, it is clearly seen that the processes described in the prior art references do not disclose or make obvious the processes of claims 10 to 16 which provide β lactitol crystals.

The process of claim 17 is "slow" compared to the prior art processes. According to the specification on page 6, bottom paragraph, the cooling may take two days or more. A person skilled in the art will understand that in such a very slow cooling, the α lactitol formation consumes all the α lactitol supersaturation in the solution and when this happens, then β lactitol crystals can be formed and can grow. The formation of β lactitol crystals is greatly enhanced by the addition of seed crystals into the solution and if that is done, as in claim 18, then the slow cooling is more certain to provide β lactitol. The β lactitol is also enhanced by certain accelerators such as lactulitol as defined in claim 20.

Thus the processes of the prior art do not disclose the processes of the present application nor do they make the obtaining of the new and totally unexpected β lactitol obvious.

Moreover, since the β lactitol as such is new and inventive, also its uses and compositions of matter containing same are new. Further, the stability, hardness, solubility and improved non-hygroscopicity of the β lactitol relative to the α lactitol are totally unexpected and this makes the compositions of matter and the use thereof in various applications inventive over the prior art use of α lactitol.

Since the prior art does not teach, disclose or suggest β lactitols or the unexpected advantages of β lactitols relative to α lactitols, the rejection of the claims under 35 U.S.C. §103 is obviated. Withdrawal thereof is respectfully requested.

Thus, in view of the Amendment to the claims, and the remarks herein; it is respectfully submitted that the present case is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

Mark J. Cohen
Registration No. 32, 211

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343

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"VERSION WITH MARKINGS TO SHOW CHANGES MADE"

IN THE CLAIMS:

Please cancel Claims 23 and 24 without prejudice.

Please amend Claims 3, 4, 10, 14, 15, and 17 as follows:

3.(Amended) Anhydrous lactitol crystals according to claim 1, characterized in having a melting point of 148-152°C, [preferably 151-152°C], a water content below 0.5% and a lactitol content of more than 99%.

4.(Amended) Anhydrous lactitol crystals according to claim 1, characterized in having a low lactulitol content [preferably below 0.5% and most preferably below 0.1% on the dry substance].

10. (Amended) A process for preparing anhydrous lactitol crystals belonging to the orthorhombic $P2_12_12_1$ crystal system and having unit cell constants about a = 9.6 Å, b = 11.1 Å, c = 14.0 Å, by crystallizing from an aqueous solution which contains not less than 70%, of lactitol on dry matter, characterized by bringing said aqueous lactitol solution to supersaturation in regard to lactitol, and subjecting the solution to crystallization conditions at a temperature between 70 and 150°C by boiling and/or cooling crystallization, allowing said solution to crystallize until a substantial first crystal yield is obtained, and conditioning said first crystal yield at a temperature of 70-100°C for a sufficient time to allow said first crystal yield to convert into a second crystal yield comprising said orthorhombic anhydrous lactitol crystals, recovering said orthorhombic anhydrous lactitol crystals from the mother liquor, and optionally washing and drying said crystals.

14. (Amended) A process for preparing anhydrous lactitol crystals belonging to the orthorhombic $P2_12_12_1$ crystal system and having unit cell constants about a = 9.6 Å, b = 11.1 Å, c = 14.0 Å, by crystallizing from an aqueous solution to which contains not less than 70%, of lactitol on dry matter, characterized by bringing said aqueous lactitol solution to supersaturation in regard to lactitol, and subjecting the solution to crystallization conditions at a temperature between 70 and 150°C by boiling and/or cooling crystallization, seeding said supersaturated solution with seed crystals of orthorhombic anhydrous lactitol and separating the resulting orthorhombic anhydrous lactitol crystals from the mother liquor, and optionally washing and drying , said product being anhydrous lactitol crystals belonging to the orthorhombic $P2_12_12_1$ crystal system and having unit cell constants about a = 9.6 Å, b = 11.1 Å, c = 14.0 Å.

15.(Amended) A process according to claim 14, [characterized by] comprising

(a) evaporating an aqueous solution of lactitol to a concentration of 80-95% by weight and to make a supersaturated solution;

(b) seeding the supersaturated solution at a temperature within the range 120-80°C [preferably 90-80°C,];

(c) optionally evaporating further while adding lactitol solution within said temperature range to increase the crystal content[, and preferably];

(d) cooling the resulting mixture [to an end temperature ranging from 70-100°C, preferably 70-80°C,];

(e) separating the orthorhombic anhydrous lactitol crystals from the mother liquor; and[,]

(f) washing and drying said crystals.

17. (Amended) A process for preparing anhydrous lactitol crystals belonging to the orthorhombic $P2_12_12_1$ crystal system and having unit cell constants about a = 9.6 Å, b = 11.1 Å, c = 14.0 Å, by crystallizing from an aqueous solution which contains not less than 70%, of lactitol on dry matter, characterized by bringing said aqueous lactitol solution to supersaturation in regard to lactitol, and subjecting said solution to slow crystallization conditions at a temperature between 150 and 70°C by slow boiling and/or cooling crystallization, recovering [the resulting] said orthorhombic anhydrous lactitol crystals from the mother liquor, and optionally washing and drying said crystals.